UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NOVARTIS INTERNATIONAL PHARMACEUTICAL AG,

Plaintiff,

v.

INCYTE CORPORATION,

Defendant.

Case No. 20-cv-00400-GHW
Hon. Gregory H. Woods

ANSWER

Defendant Incyte Corporation ("Incyte") submits this Answer to Plaintiff Novartis International Pharmaceutical AG ("Novartis")'s Complaint filed on January 15, 2020. Incyte denies each and every allegation contained in the Complaint except as may be hereinafter admitted, qualified, or explained, and states and alleges as follows:

PRELIMINARY STATEMENT

1. Paragraph 1 contains legal conclusions to which no response is required. Paragraph 1 also refers to the Collaboration and License Agreement between Novartis and Incyte (the "Agreement") and Incyte refers the Court to the operative document for its contents. Incyte specifically denies that Incyte needed Novartis' "expertise" to sell or market Jakafi or any other pharmaceutical products in the United States. To the contrary, Incyte had a sophisticated Regulatory and Development team that discovered and developed ruxolitinib—and other products—without Novartis's involvement and was prepared to bring Jakafi, and those other products, to market in the United States when it entered into the Agreement. Incyte also had the resources and capabilities to commercialize ruxolitinib in the United States. Incyte entered into the Agreement because it sought a partner to market ruxolitinib *outside* of the United States. The clause in dispute in the Agreement was negotiated and structured to incentivize and reward the

development of new inventions—patents—that could be licensed to the other party in their respective territories, through a bespoke royalty term that rewarded doing so. Incyte admits that its U.S. sales of ruxolitinib have increased substantially between 2009 and 2018, as have Novartis's sales of the drug abroad, having already resulted in a significant return on Novartis' investment. To the extent a further response is required, the allegations in Paragraph 1 are denied.

2. Incyte admits that it provided a license to Novartis to develop and commercialize certain products both inside and outside of the United States, that it retained for itself the right to develop and commercialize certain products, including Jakafi, within the United States, and that Novartis and Incyte have obligations to pay royalties to one another based on sales in their respective territories, as set forth in the Agreement. Incyte refers the Court to the operative document for its contents. While it is not common for a company to pay a royalty on its own product, here it was agreed to, for a defined period of time, to incentivize Novartis to promptly complete certain milestones under the agreement and to develop its own patents (and any such underlying improvements) both abroad and in the U.S. Indeed, the parties agreed that Novartis could use its own scientific strengths to maximize its own market for Jakavi, while also maximizing royalties it received from Incyte by obtaining and licensing to Incyte "Novartis Patent Rights" that Covered Incyte's U.S. sales of Jakafi pursuant to Section 1.79. To the extent a further response is required, the allegations in Paragraph 2 are denied.

3. Incyte admits that ruxolitinib is sold by Incyte as Jakafi® (ruxolitinib) ("Jakafi") within the U.S. and is sold by Novartis as Jakavi® (ruxolitinib) ("Jakavi") outside the U.S. Incyte admits that ruxolitinib is currently indicated for treatment of certain patient populations for three medical conditions. Incyte admits that Jakafi sales revenues in the U.S. have, since 2017, exceeded one billion dollars annually. Incyte avers that Novartis's net sales outside of the United States

have also exceed one billion annually since 2019, not including worldwide sales of the second licensed product capmatinib. Paragraph 3 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 3 are denied.

4. Incyte admits that the FDA has indicated Jakafi for treatment of (1) intermediate or high-risk myelofibrosis in adults, (2) polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea, and (3) steroid-refractory acute graft-versus-host disease in adults and pediatric patients 12 years and older. While Incyte admits certain United States patents cover Jakafi, those patents were all invented and developed by Incyte and are owned by Incyte. To date, Novartis has not invented or obtained any patents that cover Jakafi. Paragraph 4 contains legal conclusions to which no response is required. To the extent a further response is required, the allegations in Paragraph 4 are denied.

5. Paragraph 5 refers to fragmentary portions of the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 5 are denied.

6. The allegations in Paragraph 6 are denied; Incyte is entitled to reduce the royalty payments to Novartis because Incyte no longer has Regulatory Exclusivity with respect to Jakafi and because Incyte has not taken a license to any applicable Novartis United States patents and so there are no Licensed Patent Rights Covering ruxolitinib in the United States. It is Novartis who is attempting to rewrite the terms of Section 8.3(c) of the Agreement. In negotiating the Agreement, the parties expressly agreed that their intention was to create an incentive for Novartis, who had played no role in developing ruxolitinib. But Novartis could, potentially, make discoveries and obtain relevant patents—that is, develop Licensed Patent Rights Covering

ruxolitinib in the United States thereby prolonging the heightened royalty under 8.3(c)(i) and benefiting both parties. There was no intention to have Incyte take a license and pay royalties on its own patents, an irrational result for both development purposes and commercial purposes. Over the life of the agreement, Incyte has been duly paying royalties to Novartis but during that time Novartis has not made any relevant inventions, or obtained any patents covering Jakafi. Thus, because there is no longer Regulatory Exclusivity over Jakafi, Incyte is entitled to reduce its royalty payments under the terms of the Agreement.

7. Paragraph 7 contains legal conclusions to which no response is required. Paragraph 7 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. In addition, Incyte avers that Novartis's allegations relating to the expiration of the ODE status for the myelofibrosis indication is irrelevant because as the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement. To the extent a further response is required, the allegations in Paragraph 7 are denied.

THE PARTIES

8. On information and belief, the allegations of paragraph 8 are admitted.

9. The allegations of paragraph 9 are admitted.

JURISDICTION AND VENUE

10. Paragraph 10 sets forth a legal conclusion to which no response is required.

11. Paragraph 11 sets forth a legal conclusion to which no response is required.

12. Paragraph 12 sets forth a legal conclusion to which no response is required.

13. Paragraph 13 sets forth a legal conclusion to which no response is required.

FACTUAL ALLEGATIONS

A. The Agreement and Its Royalty Provisions

14. Incyte admits the parties entered the Agreement on November 24, 2009, a point when Incyte had invented ruxolitinib and was already in advanced stages of seeking FDA approval for Jakafi. Incyte also admits that it commercializes Jakafi in the U.S. for each of its three indications approved by the FDA, while it permits Novartis to commercialize its equivalent abroad under the trade name Jakavi. Paragraph 14 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Paragraph 14 also sets forth legal conclusions to which no response is required. To the extent a further response is required, the allegations in Paragraph 14 are denied.

15. Paragraph 15 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 15 are denied.

16. Incyte admits that Novartis has an obligation to make royalty payments to Incyte in relation to Novartis Territory sales, and that Incyte has an obligation to make royalty payments to Novartis based on Incyte Territory sales pursuant to the Agreement. Incyte further admits that it has paid royalties to Novartis on U.S. Jakafi sales since 2014. Paragraph 16 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 16 are denied.

17. Paragraph 17 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Incyte specifically disagrees with Paragraph 17's characterization of the purpose of Section 8.3(c) or relative importance of this "component" of the deal. Incyte further avers that (as the court has held) Regulatory Exclusivity has expired for Jakafi and that Generic

Competition, as defined in the Agreement, does not exist in the U.S. to date. To the extent a further response is required, the allegations in Paragraph 17 are denied.

18. Paragraph 18 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 18 are denied.

19. Paragraph 19 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Incyte avers that scenario "A" cannot possibly be met, as it requires that the patent claims at issue "Cover" Jakafi, a defined term *in the very sentence* referred to in "A." Novartis omits that this condition could be met only if Incyte's sales of Jakafi would infringe a patent absent a license—and Incyte's sales obviously can not infringe Incyte's own patents. In addition, Incyte avers that Novartis's allegations relating to Regulatory Exclusivity are irrelevant because, as the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement. To the extent a further response is required, the allegations in Paragraph 19 are denied.

20. Paragraph 20 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Paragraph 20 also sets forth legal conclusions to which no response is required. To the extent a further response is required, the allegations in Paragraph 20 are denied.

21. Paragraph 21 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Paragraph 21 also sets forth legal conclusions to which no response is required. In addition, Incyte avers that Novartis's allegations regarding the applicability of the Regulatory Exclusivity provision are irrelevant because as the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the

unambiguous terms of the Agreement. To the extent a further response is required, the allegations in Paragraph 21 are denied.

22. Incyte admits that the Agreement was amended on September 30, 2014. Paragraph 22 refers to the amendment to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 22 are denied.

B. The FDA's Approval of Jakafi's NDA Submissions for Three Indications

23. Incyte admits that Incyte received approval from the FDA for its June 3, 2011. Incyte avers that Incyte was already in late stages of obtaining FDA approval for Jakafi's myelofibrosis indication when the parties executed the Agreement. In addition, Incyte avers that Novartis's allegations in this Subsection B relating to what regulatory rights applied at what times are irrelevant because as the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement.

24. Incyte admits the allegations of paragraph 24. Incyte avers that it was in late stages of obtaining FDA approval before it entered the Agreement with Novartis and that it would have continued to develop and commercialize Jakafi in the United States absent involvement from Novartis, after successfully and independently commercializing ruxolitinib for the myelofibrosis indication for years in the U.S. In addition, Incyte avers that Novartis's allegations regarding the sNDAs for new indications are irrelevant because as the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement.

C. Existence of Patents and Regulatory Exclusivities for Jakafi

25. Incyte admits that it submitted its first patent application relevant to the Compounds and Jakafi in the 2005/2006 timeframe – without Novartis's assistance and years before the effective date of the Agreement. Incyte further admits Incyte's United States Patent No. 7,598,257 was submitted to the FDA's Orange Book for listing on December 1, 2011, after the FDA approved the NDA for Jakafi for the myelofibrosis indication.

26. Incyte admits Incyte's patents numbered 7598257, 8415362, 8722693, 8822481, 8829013, 9079912, 9814722, and 10016429, are currently listed on the FDA's website in its "Orange Book" listing for Jakafi. To the extent Paragraph 26 sets forth legal conclusions as to whether those patents "cover" Jakafi, no response is required. To the extent a further response is required, the allegations in Paragraph 26 are denied.

27. Paragraph 27 sets forth legal conclusions to which no response is required. To the extent a further response is required, the allegations in Paragraph 27 are denied.

28. Incyte admits that ODE-79 expires on December 4, 2021, that ODE-238 expires on May 24, 2026, and that I-799 expires on May 24, 2022. To the extent a further response is required, the allegations in Paragraph 28 are denied. As the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement.

29. Incyte admits that the ODE for its myelofibrosis indication for Jakafi in the United States expired on November 16, 2018. To the extent a further response is required, the allegations in Paragraph 29 are denied. As the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement.

30. Incyte admits that ODE-238 expires on May 24, 2026. To the extent a further response is required, the allegations in Paragraph 30 are denied. As the Court held in its Order, dated February 18, 2021 [Dkt. 50], Incyte's Regulatory Exclusivity over Jakafi has expired under the unambiguous terms of the Agreement.

D. Incyte's Royalty Reports and Payments

31. Incyte admits that Jakafi was sold in the United States in 2011. Paragraph 31 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 31 are denied.

32. Incyte admits that it submitted quarterly royalty reports and paid royalties to Novartis pursuant to the Agreement. Incyte avers that, between 2014 and 2019, it paid Novartis approximately $222.4 million in royalty payments. Paragraph 32 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. To the extent a further response is required, the allegations in Paragraph 32 are denied.

33. Incyte admits that sales of Jakafi have increased between 2011 and the present, and that it paid royalties to Novartis in 2017 and 2018 consistent with the terms of the Agreement. Paragraph 33 refers to the Agreement, and certain SEC filings made by Incyte in 2011, 2012, and 2013 and Incyte refers the Court to the operative documents for their contents. To the extent a further response is required, the allegation in Paragraph 33 are denied.

34. Incyte admits that net annual sales were approximately $1.1 billion for the 2017 fiscal year, and that it paid royalties to Novartis of about $50.5 million. Incyte avers that, in that fiscal year, Novartis's Annual Net Sales for Jakavi outside the U.S. were approximately $777 million. To the extent a further response is required, the allegations in Paragraph 34 are denied.

35. Incyte admits that net annual sales were approximately $1.4 billion for the 2018 fiscal year, and that it paid royalties to Novartis of about $62.9 million. Incyte avers that, in that fiscal year, Novartis's Annual Net Sales for Jakavi outside the U.S. were approximately $977 million. To the extent a further response is required, the allegations in Paragraph 35 are denied.

36. Paragraph 36 refers, in part, to an earnings call and Incyte refers the Court to the transcript of the earnings call for its contents. Incyte is without knowledge or information sufficient to form a belief as to the truth of Novartis's expectations and those of unnamed analysts. To the extent a further response is required, the allegations in Paragraph 36 are denied.

37. Incyte admits that on or about May 1, 2019, Incyte sent a royalty report for the quarter ending March 31, 2019 and that Novartis issued an invoice on or around May 6, 2019. The allegations in Paragraph 37 are otherwise denied.

38. Incyte admits that it sent a revised royalty report on or about May 16, 2019. Incyte avers that there is no requirement among the parties, nor any precedent in their prior course of performance, for "prior notice" of either a revised royalty report or of application of the 50% royalty reduction under Section 8.3(c). The allegations in Paragraph 38 are otherwise denied.

39. Incyte admits that Novartis disputed Incyte's revised royalty calculations. Incyte avers that the Court, in its Order, dated February 18, 2021 [Dkt. 50], held that the expiration of the myelofibrosis indication did result in the expiration of Regulatory Exclusivity over Jakafi under the ambiguous terms of the Agreement. The allegations in Paragraph 39 are otherwise denied.

40. Incyte admits that on or about August 13, 2019, Incyte sent a royalty report for the quarter ending June 20, 2019 to Novartis that reflected a royalty rate of 2.5%. The allegations in Paragraph 40 are otherwise denied.

41. Paragraph 41 refers to a letter dated August 20, 2019, and Incyte refers the Court to the letter for its contents. To the extent a further response is required, the allegations in Paragraph 41 are otherwise denied.

42. Incyte admits that it reported a royalty, at the 2.5% rate, of about $10.6 million for the third quarter of 2019. Incyte also admits that $10.6 million is 50% of $21.2 million. The allegations in Paragraph 42 are otherwise denied.

43. Incyte admits that it did not send notice of the Step Down prior to the myelofibrosis ODE expiration. Incyte avers that there is no requirement or precedent in the parties' conduct for such notice. Incyte avers that the "half a year" between the expiration of myelofibrosis ODE expiration and Incyte's application of the Step Down is the very process specifically contemplated by the Section 8.3 of the Agreement, because the Step Down only took effect under the Agreement upon January 1 of the calendar year following the ODE expiration, and Incyte's first royalty report was not due until after the first quarter of that year. The allegations in Paragraph 43 are otherwise denied.

44. The allegations in Paragraph 44 are denied. Incyte avers that the parties expressly agreed to the interpretation of the contract Incyte takes at the time of the negotiations, because it would properly incentivize Novartis to make inventions and obtain its own U.S. patents on product improvements that would benefit both parties.

E. Compliance with the Dispute Resolution Process Set Forth in the Agreement

45. Paragraph 45 refers to the Agreement and correspondence dated August 21, 2019, and Incyte refers the Court to the operative documents for their contents. Incyte admits that its General Counsel and General Counsel for Novartis engaged in discussions regarding the royalty

dispute on or about July 26, 2019, and that the issues were escalated to the Executive Officer level. To the extent a further response is required, the allegations in Paragraph 45 are denied.

46. Incyte admits that representatives of Incyte and those of Novartis have conferred regarding the purported royalties that Incyte owes. To the extent a further response is required, the allegations in Paragraph 46 are denied.

47. Paragraph 47 refers to the Agreement, and Incyte refers the Court to the operative documents for its contents. To the extent a further response is required, the allegations in Paragraph 47 are admitted.

FIRST CAUSE OF ACTION

Breach of Contract

48. The responses to the allegations set forth in the foregoing paragraphs are restated and incorporated by reference.

49. Incyte admits that the Agreement is an enforceable contract that was negotiated at arms' length. To the extent a further response is required, the allegations in Paragraph 49 are denied.

50. Paragraph 50 refers to the Agreement, and Incyte refers the Court to the operative document for its contents. Paragraph 50 contains legal conclusions to which no response is required. To the extent a further response is required, the allegations in Paragraph 52 are denied.

51. The allegations in Paragraph 51 are denied.

52. The allegations in Paragraph 52 are denied; Incyte has complied with its obligations under the Agreement.

53. Incyte admits Novartis has availed itself of the contractual dispute resolution procedures of the Agreement. Incyte otherwise denies the allegations of Paragraph 53.

54. Incyte is without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 54.

SECOND CAUSE OF ACTION

Declaratory Judgment

55. The responses to the allegations set forth in the foregoing paragraphs are restated and incorporated them by reference.

56. Incyte admits that Novartis has disputed Incyte's right to invoke the Step Down. However, pursuant to Section 8.3(c) of the Agreement, Incyte is entitled to a 50% reduction of the royalties that it pays to Novartis, resulting in a 2.5% rate. To the extent a further response is required, the allegations in Paragraph 56 are denied.

57. Incyte admits that there is an actual and justiciable controversy between Novartis and Incyte to the extent that Novartis is seeking royalty payments to which it is not entitled under the Agreement. The allegations in Paragraph 57 are otherwise denied.

58. Paragraph 58 contains a legal conclusion to which no response is required. To the extent a response is required, the allegations in Paragraph 58 are denied; resolution of this dispute will aid in the termination of this controversy by making clear to Novartis that Incyte has, at all times, complied with its obligations to pay royalties to Novartis.

59. Incyte admits that it will continue to invoke the Step Down. Incyte avers that it is entitled to reduce the royalty rate it pays to Novartis because Incyte no longer has Regulatory Exclusivity and because no Licensed Product is Covered by a Valid Claim of Licensed Patent Rights pursuant to Section 8.3(c) of the Agreement. Except as so admitted, Incyte denies the allegations of Paragraph 59.

60. Incyte admits that there is no other pending litigation between Novartis and Incyte with respect to royalties owed by either side under the Agreement.

61. Paragraph 61 contains legal conclusions to which no response is required. To the extent a response is required, Incyte admits that the issuance of a declaratory judgment can resolve the current controversy by establishing that Incyte's royalty payments were, at all times, consistent with the terms of the Agreement.

AFFIRMATIVE DEFENSES

The following are defenses that Incyte may assert based on the facts alleged in the action, or based on facts adduced in discovery. In disclosing these defenses, Incyte does not assume any burden of proof not otherwise required by law. Moreover, Incyte undertakes the burden of proof only as to those defenses deemed "affirmative" defenses by law, regardless of how such defenses are denominated herein. Finally, Incyte reserves its right to assert further defenses that may become apparent in the course of discovery or at trial.

FIRST AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Novartis's claims are barred, in whole or in part, because any and all actions taken by Incyte were, at all times, lawful, proper, and consistent with Incyte's duties and obligations, including those set forth in the Agreement.

SECOND AFFIRMATIVE DEFENSE
(No Injury)

Novartis's claims are barred because it has not suffered any injury in fact as a result of any of Incyte's alleged acts or failure to act.

THIRD AFFIRMATIVE DEFENSE
(Unjust Enrichment)

Novartis's claims are barred because any recovery would result in unjust enrichment to Novartis, which has already received the royalty payments that it is due under the Agreement.

FOURTH AFFIRMATIVE DEFENSE
(Unclean Hands)

Novartis's claims are barred, in whole or in part, by the doctrines of estoppel, waiver, release and/or unclean hands.

FIFTH AFFIRMATIVE DEFENSE
(False Claims)

Novartis's claims are barred, in whole or in part, because, they are based on allegations that are materially false.

Dated: March 22, 2021
New York, New York

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